REMARKS

In the Office Action, claims 18-22 were withdrawn from consideration. The Action, however, did not provide sufficient grounds to make this withdrawal, however, simply concluding that the new claims were directed to an invention that is independent or distinct from the originally claimed invention. This conclusion was stated as merely based on the fact that the withdrawn claims are drawn to a method instead of the apparatus. The statement was also made in the office action, citing M.P.E.P. § 821.03, that claims 18-22 are directed to a non-elected invention, although there is no previous restriction or election requirement in the file.

M.P.E.P. § 821.03 is concerned with claims that are added for a distinct inventions. But this section does not cover the burden or the test for distinctness required to withdraw a group of claims from consideration. M.P.E.P. § 806.05(e) should have been consulted where the question arose about process and apparatus claim distinctness. This section provides the tests that need to be satisfied to find process or method claims and apparatus claims as being drawn to independent and distinct inventions. The burden of making this a proper showing is placed squarely on the Examiner, as is the burden "to provide Reasonable examples that recite material differences," between the claim groups. M.P.E.P. § 806.05(e).

Consequently, claims 18-22 have not been properly withdrawn from consideration and should have been examined in the Office Action. The Examiner has not met the burden required. Thus, the final status of the present Office Action should be withdrawn.

Claims 1-3, 6, 7, 9-13, and 16 were rejected under 35 U.S.C. § 102(b) as anticipated by Richmond. Claims 1, 4, and 5 were also rejected under section 102(b) as anticipated by Huber. Claim 1 has been amended to claim that the device is a jet injector that comprises the medicament cartridge. This is supported in the originally filed abstract of the application, which discloses two embodiments, one of which is a syringe, and another of which is a jet injector. Thus, present claim 1 is just directed to the preferred jet injector. This definition of the jet injector in the preamble also must be considered as a structural recitation because it is not merely a statement of intended use.

It is well known in the art that jet injectors inject medicaments by creating a high speed jet of the medicament that penetrates the tissue of the patient as a jet to a significant distance beyond the end of the injector. Some jet injectors are called needle-

assisted jet-injectors because then use a needle to penetrate the patient tissue by a short distance, and the energy created in the jet is used to fire the medicament significantly deeper into the tissue. It is also known that jet injectors require certain components to generate the short duration, high-power firing stroke to generate sufficient pressure to drive the fluid out in a sufficiently powerful jet. These components include, for instance, an energy source to drive the plunger when the injector is fired, a trigger to allow a user to fire the injector, and carefully dimensioned and configured jet nozzle to efficiently form the high speed jet. Due to the high speed and pressure requirements for jet injectors, they are not powered by pressing directly on a plunger by hand. New claim 23 further clarifies that the jet injector is configured for jet injection of the medicament from the fluid pathway.

Both Richmond and Huber are directed to syringes, and neither teaches or suggests a jet injector, which is defined in claim 1. In particular, Richmond discloses a sequential delivery syringe with a plurality of stoppers with piercing devices to sequentially deliver different solutions in the various compartments, one after the other. The plunger of the syringe is powered by hand. There is no motivation to combine this teaching with any jet injector because a slow delivery of each solution is a function of the structure of this device. The sequential delivery of the drugs in each compartment would lead to undesirable pulsing in the intensity of a jet, which could hinder precise delivery to a desired depth in the tissue. Also, the series of thin needles of the Richmond piercing devices and the flow path through the interior of each stopper produces a significant loss of energy, that would seriously slow and extract power from the jet mechanism. There is also no teaching of modifying the device to have any of the remaining parts used in a jet injector. Thus, one of skill in the art would not find any teaching, suggestion, or motivation to use this very energy-inefficient system in a jet injector.

The subject matter of claim 24 is also patentably distinct from Richmond, which neither teaches nor suggests making the first stopper to substantially prevent any of the medicament contained in the cartridge from contacting the needle prior to the firing of the jet injector. The forwardmost stopper in Richmond does not keep the solution in compartment D from contacting the needle 30. Claim 24 provides the surprising advantage over Richmond that the sterility of any medicament within the cartridge can be maintained until the injector is fired. This is not possible in Richmond because compartment D is open to the atmosphere and forwardmost needle. Additionally, as disclosed in the specification of the present application, certain medicaments, such as those containing insoluble particles, tend to clog

the needle if in contact therewith prior to injection, and claim 24 thus provides the additional surprising advantage over Richmond that these types of medicaments can be more reliably employed.

Claim 26 further defines that the medicament cartridge comprises only the two stoppers that contain the medicament therebetween, and claim 27 additionally recites that the medicament cartridge is configured such that all of the medicament in the cartridge is injected together. Claim 28 recites that the first stopper is free of any device to puncture another of the stoppers. The invention of each of these claims is contrary to the teaching of Richmond, which requires many stoppers to inject different drugs, one after the other. Richmond teaches away from injecting all of the medicament together, and its purpose is defeated by providing only two stoppers that contain all of the medicament therebetween or by having the first stopper free of any piercing device. Thus, these claims are also patentably distinct from Richmond on their own merits.

Each of new claims 23-28 is supported, for example, by the disclosure of the embodiment of Fig. 1. New claim 29 is supported in the disclosure of the embodiment of Fig. 10.

With respect to Huber, this reference also has several teachings that make it incompatible with, and that provide no teaching, suggestion, or motivation of, replacing the manually operated plunger with the required high energy firing device of a jet injector. For instance, Huber teaches an aspirating syringe which is designed to aspirate from the injection site prior to injecting so that the aspirated matter is visible within the syringe. In a jet injector, any injecting needle is not long enough to reach the injection site by definition, because the jet itself forces the medicament deeper than the needle.

Additionally, as described in column 4 of the Huber patent, the structure of the syringe and the teaching is for allowing the syringe to be held aiming upward to then apply pressure against the plunger to cause liquid to enter the dry forward compartment. The syringe is then meant to be shaken, and the medication must be allowed to dissolve. Then residual air is then expelled through the needle. After that, the aspiration takes place, possibly more than once. All of these various required movements of the plunger, Huber further teaches away from jet injectors, in which activation of the plunger is by a high power energy source that moves the plunger quickly and sufficiently to perform an injection. It is not clear from these complex movements and long periods of time required for and between each plunger movement, such as to reconstitute the medication, could be made to work with

the fast activation and fast firing mechanism of a jet injector. As a result, the present claims are not anticipated nor rendered obvious over Huber.

The subject matter of claims 24 and 26 is also patentably distinct from Huber. Huber neither teaches nor suggests making the first stopper to substantially prevent any of the medicament contained in the cartridge from contacting the needle prior to the firing of the jet injector, as defined in claim 24. The only stopper 46 that is pierce by needle 14 is pierced only after the stopple 39 is pierced, and thus after the medicament is in contact with the needle. As discussed above, many steps need to take place prior to the Huber syringe being ready to inject the medicament. Claim 24 provides the surprising advantage of allowing sterility of the medicament within the cartridge until the moment of firing, which is neither possible nor desired in Huber, which requires the various steps, including air release, dissolving of the medication, and aspiration prior to injection. Additionally, as disclosed in the specification of the present application, certain medicaments, such as those containing insoluble particles, tend to clog the needle if in contact therewith prior to injection, and claim 24 thus provides the surprising advantage over Huber that these types of medicaments can more reliably be employed.

Claim 26 is also patentable over Huber, because removing the stopper 46 or stopple 38 would render the device inoperable for the intended purpose. Removing the stopper would not allow the liquid to be kept separate from the medication, and removing the stopper would not contain the medication at all.

Claim 15 was rejected under 35 U.S.C. § 103(a), as obvious over Richmond in view of Vetter '490. First, Vetter does not remedy the deficiencies of Richmond discussed above.

The rejection alleges that Vetter teaches insoluble particles, based on the disclosure of lyophilizing off the solution in column 3. As explained in the application's specification, medicaments containing insoluble particles often clog injection needles if in contact therewith prior to injection, which is especially critical in a jet injector, since jet injectors rely on a clean and predictable injection conduit to properly form and expel the high speed and high energy jet. The Vetter disclosure teaches that the medicament is in solution, and the lyophilizing occurs from the solution. Thus, this is contrary to the teaching of insoluble particles.

Furthermore, Richmond requires injecting a series of drugs one after the other. Richmond is not readily modifiable to use the system of Vetter and still maintain this

capability. Such a modification is not possible without undue additional experimentation and invention. For example, if the Vetter open groove 19 were used in Richmond, the various drugs would start combining with each other and would not be sequentially injectable. Thus, there is no motivation to combine these references, and any combination would defeat the Richmond teaching and renders it inoperative for it intended purpose.

Finally, claim 17 was rejected under section 103(a) as obvious over Huber in view of Tanaka. Tanaka does not remedy the deficiencies of Huber, and together do not result in the invention of any of the present claims.

Consequently, as indicated above, it is respectfully requested that the final status of the rejection be withdrawn. All claims are consequently presently believed to be in condition for allowance.

Respectfully submitted,

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